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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YUKIHIKO SAEKI, YUICHIRO TABUNOKI,
and TOMOYUKI KOSHI

Appeal 2010-004349
Application 10/566,253
Technology Center 1600

Before ERIC GRIMES, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, Administrative Patent Judges.

FREDMAN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for inhibiting osteopontin production. The Examiner rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

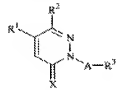
Statement of the Case

Background

"This invention relates to a method of inhibiting the production of osteopontin, and specifically to a preventive and therapeutic method of diseases resulting from enhanced production of osteopontin" (Spec. 1, ll. 6-9).

The Claims

Claims 1-4 and 29-34 are on appeal. Claim 1 is representative and reads as follows:

> 1. A method of inhibiting osteopontin (OPN) production, comprising administering to a subject in need thereof an effective amount of a pyridazine derivative represented by the following formula (I) or a salt thereof:
>
> 
>
> (I)
>
> wherein:
>
> R^1 is a phenyl or pyridyl group which may be substituted by 1 to 3 substituents selected from halogen atoms and C_{1-6} alkoxy groups;
>
> R^2 is a phenyl group which may be substituted at the 4-position thereof with a C_{1-6} alkoxy group or C_{1-6} alkoxythio group and may also be substituted at one or two other positions thereof a like number of substituents selected from halogen atoms, C_{1-6} alkoxy groups and C_{1-6} alkoxythio groups;
>
> R^3 is a hydrogen atom; a C_{1-6} alkoxy group; a halogenated C_{1-6} alkyl group; a C_{3-6} cycloalkyl

group; a phenyl, pyridyl or phenyloxy group, each of which may be substituted by 1 to 3 substituents selected from halogen atoms, C_{1-6} alkyl groups, C_{1-6} alkoxy groups, carboxyl groups, C_{2-7} alkoxycarbonyl groups, nitro groups, amino groups, C_{1-6} alkylamino groups and C_{1-6} alkylthio groups; a substituted or unsubstituted piperidino, a substituted or unsubstituted piperidyl, a substituted or unsubstituted piperazino or a substituted or unsubstituted morpholino group; a substituted or unsubstituted aminocarbonyl group; a C_{2-7} alkylcarbonyl group; or a substituted or unsubstituted piperazinocarbonyl group;

A is a single bond, a C_{1-6} linear or branched alkylene group, or a C_{2-9} linear or branched alkenylene group; and

X is an oxygen atom or a sulfur atom, with a proviso that A is a single bond when R^3 is a halogenated C_{1-6} alkyl group.

The issues

A. The Examiner rejected claims 1-4 and 29-34 under 35 U.S.C. § 102(b) as anticipated by Ohkuchi[1] as evidenced by Ashkar[2] (Ans. 4-5).

B. The Examiner rejected claim 34 under 35 U.S.C. § 103(a) as obvious over Ohkuchi and McPhaden[3] (Ans. 5-7).

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[1] Ohkuchi et al., US 6,348,468 B1, issued Feb. 19, 2002.
[2] Ashkar et al., WO 00/63241 A2, published Oct. 26, 2000.
[3] McPhaden et al., Plasma Osteopontin Levels in Multiple Myeloma, 84 (10, Supp. 1) BLOOD 172a, abstract #674 (1994).

A. 35 U.S.C. § 102(b)

The Examiner finds that "Ohkuchi et al. teach pyridazine derivative compounds, including applicant's elected compound species, 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one, and methods of treatment comprising administering said compounds" (Ans. 4). The Examiner finds that to "the extent that Ohkuchi et al. teach the same compounds to treat the same patient population (patients with kidney disease, e.g. ischemic nephritis) as the instant application, the preamble of claims 1 and 29 are inherent" (id. at 5). The Examiner finds that "Ashkar et al. (WO 00/63241) is added as an evidentiary reference only to show that kidney disease (i.e. glomerulonephritis) and arthritis are modulated by osteopontin (OPN)" (id.).

Appellants contend that Ohkuchi "is drawn to treating a universe of subjects in which interleukin-1β production is implicated. There is nothing in the prior art to suggest any nexus between interleukin-1β production and OPN production" (App. Br. 6). Appellants contend that "Claim 33 is limited by the requirement that the members of the disease Markush group require that it result from enhanced OPN production. There are, of course, many kidney diseases. Ischemic nephritis has not been shown to result from enhanced OPN production" (id.). Appellants contend that the fact that "the specific OPN modulator compounds of Ashkar et al are disclosed to have a utility against specific diseases in no way suggests that particular compounds disclosed as having inhibitory activity only against interleukin-1β production would be reasonably expected to have such activity against OPN production" (id. at 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the Ohkuchi anticipates claim 1?

Findings of Fact

1. Ohkuchi teaches "[p]reparation of 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazine-3-thione" (Ohkuchi, col. 54, ll. 13-24).

2. Ohkuchi teaches "a pharmaceutical composition comprising the pyridazine derivative (1) or the salt thereof and a pharmaceutically acceptable carrier" (Ohkuchi, col. 3, ll. 1-4).

3. Ohkuchi teaches a "pharmaceutical composition for inhibiting interleukin-1β production in a mammal" (Ohkuchi, col. 70, ll. 15-16).4. Ohkuchi teaches that the "pyridazine derivatives . . . have excellent inhibitory activity against interleukin-1β production, and are useful for the prevention and treatment of diseases caused by stimulation of interleukin-1β production, for example . . . ischemic nephritis" (Ohkuchi, col. 13, ll. 10-20). 5. The Examiner finds that to "the extent that Ohkuchi et al. teach the same compounds to treat the same patient population (patients with kidney disease, e.g. ischemic nephritis) as the instant application, the preamble of claims 1 and 29 are inherent" (Ans. 5). 6. Ashkar teaches "administering to the patient or subject an Eta-1/osteopontin inhibitory modulator such that the type-l immune response is downregulated" (Ashkar 8, ll. 18-19).

7. Ashkar teaches that "[e]xemplary diseases and/or disorders from which a patient, as defined herein, may be at risk for, have or be

suffering from include but are not limited . . . various forms of glomerulonephritis" (Ashkar 17, ll. 7-13).

Principles of Law

"Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." MEHL/Biophile Int'l. Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (quoting In re Oelrich, 666 F.2d 578, 581 (CCPA 1981)).

Analysis

The Examiner finds that "[t]o the extent that Ohkuchi et al. teach the same compounds to treat the same patient population (patients with kidney disease, e.g. ischemic nephritis) as the instant application, the preamble of claims 1 and 29 are inherent" (Ans. 5). The Examiner cites Ashkar to show that a particular kidney disease, glomerulonephritis, is regulated by osteopontin (FF 6-7; Ans. 5).

Appellants contend that "[t]here are, of course, many kidney diseases. Ischemic nephritis has not been shown to result from enhanced OPN production" (App. Br. 6).

We conclude that Appellants have the better position. We agree with Appellants' interpretation of independent claims 1 and 29 to require that the "subject in need thereof" limits the universe of subjects to those in need of inhibition of osteopontin production (see App. Br. 6). While the Examiner attempted to address this issue in citing Ashkar, even the evidence cited by the Examiner demonstrates the existence of two different types of kidney disease, glomerulonephritis and ischemic nephritis, only one of which is

demonstrated to be regulated by osteopontin (FF 6-7). The Examiner has therefore failed to demonstrate that the ischemic nephritis patient population of Ohkuchi, who would be treated to inhibit interleukin-1β production with the pyridazine derivatives, is necessarily a population which requires inhibition of osteopontin production.

At best, we are left with the possibility that the population of patients with ischemic nephritis might have upregulated osteopontin production similar to those patients with glomerulonephritis. This is insufficient to support an inherency rejection. As noted above, inherency cannot be established by showing that the asserted limitation is merely probable or possible. In re Oelrich, 666 F.2d at 581. The Examiner has presented no evidence that any of the list of diseases in column 13 of Ohkuchi necessarily result in increased osteopontin production. We are therefore constrained to reverse this rejection.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that Ohkuchi anticipates claim 1.

B. 35 U.S.C. § 103(a) over Ohkuchi and McPhaden

The Examiner finds it obvious "to treat multiple myeloma as taught by McPhaden et al. with the method of treatment comprising administering a compound in a therapeutically effective amount as taught by Ohkuchi et al. (e.g. applicant's elected compound) to treat multiple myeloma" (Ans. 6). The Examiner finds that "[o]ne would have been motivated to treat multiple myeloma . . . because McPhaden suggest that IL-1 beta is an osteoclastic activating factor that is implicated in multiple

myeloma and Ohkuchi et al. teach the instant compounds are effective in treating IL-1 beta related conditions" (Ans. 6).

Appellants contend that "[n]either McPhaden et al, nor any other prior art, discloses any connection or nexus between inhibiting interleukin-1β production, as disclosed by Ohkuchi et al, and inhibiting OPN production" (App. Br. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Ohkuchi and McPhaden render claim 34 obvious?

Findings of Fact

8. McPhaden teaches that a "number of osteoclast activating factors have been implicated in multiple myeloma including IL-6, IL-1β, TNF and TGFβ. One or more of these factors may upregulate OPN production from osteoblasts or osteoclasts. Further study is needed to clarify the source and regulation of OPN in myeloma patients." (McPhaden, abstract).

9. McPhaden teaches that "[o]ur results suggest that plasma OPN may be a useful clinical marker for disease severity in multiple myeloma" (McPhaden, abstract).

Principles of Law

An invention

> composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art…. [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.